

## Vabysmo™ (faricimab-svoa) (Intravitreal)

Document Number: IH-0659

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### I. Length of Authorization

Coverage will be provided annually and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [NDC unit]:

- 2 mg injection: 1 vial per eye every 28 days

#### B. Max Units (per dose and over time) [HCPCS Unit]:

| Diagnosis                                          | MU for Initial Dosing                            | MU for Maintenance Dosing              |
|----------------------------------------------------|--------------------------------------------------|----------------------------------------|
| Neovascular age-related macular degeneration (AMD) | 60 billable units (6 mg) every 28 days x 4 doses | 60 billable units (6 mg) every 28 days |
| Diabetic Macular Edema (DME)                       | 60 billable units (6 mg) every 28 days x 6 doses | 60 billable units (6 mg) every 28 days |

*(Max units are based on administration to both eyes)*

### III. Initial Approval Criteria<sup>1-8</sup>

Coverage is provided in the following conditions:

- Patient has tried and failed treatment with Avastin (bevacizumab) or a or a documented contraindication to its use exists; **AND**
- Patient is at least 18 years of age; **AND**

#### Universal Criteria

- Patient is free of ocular and/or peri-ocular infections; **AND**
- Patient does not have active intraocular inflammation; **AND**
- Therapy will not be used with other ophthalmic VEGF inhibitors (i.e., aflibercept, brolocizumab-dblb, ranibizumab, pegaptanib, bevacizumab, etc.); **AND**
- Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment; **AND**
- Patient has a definitive diagnosis of one of the following:

## Neovascular (Wet) Age-Related Macular Degeneration (nAMD) †\*

## Diabetic Macular Edema (DME) †\*

*\*Patients with an insufficient response during initial therapy administered every 4 weeks for at least 4 doses may continue with dosing every 4 weeks. Patients with loss of response to maintenance therapy administered at less frequent intervals may increase the dosing frequency in a step-wise manner until response is regained. (Refer to Section V)*

† FDA Approved Indication(s)

### IV. Renewal Criteria <sup>1-8</sup>

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and indication-specific relevant criteria as identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: endophthalmitis and retinal detachments, increase in intraocular pressure, arterial thromboembolic events (ATE), etc.; **AND**
- Patient has had a beneficial response to therapy (e.g., improvement in the baseline best corrected visual acuity (BCVA), etc.) and continued administration is necessary for the maintenance treatment of the condition

### V. Dosage/Administration <sup>1</sup>

| Indication             | Dose                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| nAMD                   | <p><u>Initiation:</u></p> <ul style="list-style-type: none"><li>• 6 mg intravitreally per affected eye once every 4 weeks (approximately every 28 days <math>\pm</math>7 days, monthly) for the first four doses (16 weeks or 4 months)</li></ul> <p><u>Maintenance:</u></p> <ul style="list-style-type: none"><li>• Follow the initial four doses with optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to ascertain whether to give a 6 mg dose via intravitreal injection on one of the following three regimens:<ul style="list-style-type: none"><li>– Weeks 28 and 44 (every 16 weeks); or</li><li>– Weeks 24, 36 and 48 (every 12 weeks); or</li><li>– Weeks 20, 28, 36 and 44 (every 8 weeks)</li></ul></li></ul> <p><u>Note:</u> Additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (approximately monthly) dosing after the first four doses (16 weeks or 4 months).</p> |
| Diabetic macular edema | <ul style="list-style-type: none"><li>• 6 mg intravitreally per affected eye once every 4 weeks (approximately every 28 days <math>\pm</math>7 days, monthly) for at least four doses. If after at least 4 doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations through week 52; <b>OR</b></p> <ul style="list-style-type: none"> <li>6 mg intravitreally per affected eye once every 4 weeks (approximately every 28 days <math>\pm</math>7 days, monthly) for the first six doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months) over the next 28 weeks.</li> </ul> <p><u>Note:</u> Additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first four doses.</p> |
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## VI. Billing Code/Availability Information

### HCPCS Code:

- J3590 – Unclassified biologics
- C9097 – Injection, faricimab-svoa, 0.1 mg; 1 billable unit = 0.1 mg (*Effective 07/01/2022*)
- C9399 – Unclassified drugs or biologicals (*Discontinue use on 07/01/2022*)

### NDC:

- Vabysmo 6 mg/0.05 mL (concentration 120 mg/mL) solution for injection, overfilled single-use vial: 50242 -0096-xx

## VII. References

- Vabysmo [package insert]. South San Francisco, CA; Genentech, Inc.; January 2022. Accessed January 2022.
- Solomon SD, Chew E, Duh EJ, et al. Diabetic Retinopathy: A Position Statement by the American Diabetes Association. *Diabetes Care*. 2017 Mar;40(3):412-418.
- American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Panel, Hoskins Center for Quality Eye Care. Diabetic Retinopathy PPP – Update 2017. Nov 2017.
- American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Panel, Hoskins Center for Quality Eye Care. Retinal Vein Occlusions PPP – Update 2017. Nov 2017.
- American Academy of Ophthalmology-Preferred Practice Patterns (AAO-PPP) Retina/Vitreous Panel, Hoskins Center for Quality Eye Care. Age-Related Macular Degeneration PPP – Update 2017. Nov 2017.
- Royal College of Ophthalmologists. Clinical Guidelines – Retinal Vein Occlusion (RVO) Guidelines – July 2015. Accessed at <https://www.rcophth.ac.uk/standards-publications-research/clinical-guidelines>.
- Heier JS, Khanani AM, Quezada et al; TENAYA and LUCERNE Investigators. Efficacy, durability, and safety of intravitreal faricimab up to every 16 weeks for neovascular age-related macular degeneration (TENAYA and LUCERNE): two randomised, double-masked, phase 3, non-inferiority trials. *Lancet*. 2022 Jan 21. pii: S0140-6736(22)00010-1. doi: 10.1016/S0140-6736(22)00010-1.

8. Wykoff CC, Abreu F, Adamis AP, et al; YOSEMITE and RHINE Investigators. Efficacy, durability, and safety of intravitreal faricimab with extended dosing up to every 16 weeks in patients with diabetic macular oedema (YOSEMITE and RHINE): two randomised, double-masked, phase 3 trials. *Lancet*. 2022 Jan 21. pii: S0140-6736(22)00018-6. doi: 10.1016/S0140-6736(22)00018-6.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10   | ICD-10 Description                                                                                                                    |
|----------|---------------------------------------------------------------------------------------------------------------------------------------|
| E08.311  | Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema                                |
| E08.3211 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye           |
| E08.3212 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, left eye            |
| E08.3213 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, bilateral           |
| E08.3219 | Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye     |
| E08.3311 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, right eye       |
| E08.3312 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, left eye        |
| E08.3313 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, bilateral       |
| E08.3319 | Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E08.3411 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, right eye         |
| E08.3412 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, left eye          |
| E08.3413 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, bilateral         |
| E08.3419 | Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye   |
| E08.3511 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, right eye                   |
| E08.3512 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, left eye                    |
| E08.3513 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, bilateral                   |
| E08.3519 | Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, unspecified eye             |
| E09.311  | Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema                                   |
| E09.3211 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye              |
| E09.3212 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye               |
| E09.3213 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral              |

| ICD-10   | ICD-10 Description                                                                                                                 |
|----------|------------------------------------------------------------------------------------------------------------------------------------|
| E09.3219 | Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye     |
| E09.3311 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye       |
| E09.3312 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye        |
| E09.3313 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral       |
| E09.3319 | Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E09.3411 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye         |
| E09.3412 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye          |
| E09.3413 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral         |
| E09.3419 | Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye   |
| E09.3511 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye                   |
| E09.3512 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye                    |
| E09.3513 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral                   |
| E09.3519 | Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye             |
| E10.311  | Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema                                                  |
| E10.3211 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye                             |
| E10.3212 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye                              |
| E10.3213 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral                             |
| E10.3219 | Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye                       |
| E10.3311 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye                         |
| E10.3312 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye                          |
| E10.3313 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral                         |
| E10.3319 | Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye                   |
| E10.3411 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye                           |
| E10.3412 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye                            |
| E10.3413 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral                           |
| E10.3419 | Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye                     |
| E10.3511 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye                                     |

| ICD-10   | ICD-10 Description                                                                                                        |
|----------|---------------------------------------------------------------------------------------------------------------------------|
| E10.3512 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye                             |
| E10.3513 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral                            |
| E10.3519 | Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye                      |
| E11.311  | Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema                                         |
| E11.3211 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye                    |
| E11.3212 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye                     |
| E11.3213 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral                    |
| E11.3219 | Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye              |
| E11.3311 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye                |
| E11.3312 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye                 |
| E11.3313 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral                |
| E11.3319 | Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye          |
| E11.3411 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye                  |
| E11.3412 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye                   |
| E11.3413 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral                  |
| E11.3419 | Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye            |
| E11.3511 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye                            |
| E11.3512 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye                             |
| E11.3513 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral                            |
| E11.3519 | Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye                      |
| E13.311  | Other specified diabetes mellitus with unspecified diabetic retinopathy with macular edema                                |
| E13.3211 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye           |
| E13.3212 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye            |
| E13.3213 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral           |
| E13.3219 | Other specified diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye     |
| E13.3311 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye       |
| E13.3312 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye        |
| E13.3313 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral       |
| E13.3319 | Other specified diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye |



| ICD-10   | ICD-10 Description                                                                                                      |
|----------|-------------------------------------------------------------------------------------------------------------------------|
| E13.3411 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye       |
| E13.3412 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye        |
| E13.3413 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral       |
| E13.3419 | Other specified diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye |
| E13.3511 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye                 |
| E13.3512 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye                  |
| E13.3513 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral                 |
| E13.3519 | Other specified diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye           |
| H35.3210 | Exudative age-related macular degeneration, right eye, stage unspecified                                                |
| H35.3211 | Exudative age-related macular degeneration, right eye, with active choroidal neovascularization                         |
| H35.3212 | Exudative age-related macular degeneration, right eye, with inactive choroidal neovascularization                       |
| H35.3213 | Exudative age-related macular degeneration, right eye, with inactive scar                                               |
| H35.3220 | Exudative age-related macular degeneration, left eye, stage unspecified                                                 |
| H35.3221 | Exudative age-related macular degeneration, left eye, with active choroidal neovascularization                          |
| H35.3222 | Exudative age-related macular degeneration, left eye, with inactive choroidal neovascularization                        |
| H35.3223 | Exudative age-related macular degeneration, left eye, with inactive scar                                                |
| H35.3230 | Exudative age-related macular degeneration, bilateral, stage unspecified                                                |
| H35.3231 | Exudative age-related macular degeneration, bilateral, with active choroidal neovascularization                         |
| H35.3232 | Exudative age-related macular degeneration, bilateral, with inactive choroidal neovascularization                       |
| H35.3233 | Exudative age-related macular degeneration, bilateral, with inactive scar                                               |
| H35.3290 | Exudative age-related macular degeneration, unspecified eye, stage unspecified                                          |
| H35.3291 | Exudative age-related macular degeneration, unspecified eye, with active choroidal neovascularization                   |
| H35.3292 | Exudative age-related macular degeneration, unspecified eye, with inactive choroidal neovascularization                 |
| H35.3293 | Exudative age-related macular degeneration, unspecified eye, with inactive scar                                         |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |                                                                                             |                                                   |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------|---------------------------------------------------|
| Jurisdiction                                                  | Applicable State/US Territory                                                               | Contractor                                        |
| E (1)                                                         | CA, HI, NV, AS, GU, CNMI                                                                    | Noridian Healthcare Solutions, LLC                |
| F (2 & 3)                                                     | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ                                                      | Noridian Healthcare Solutions, LLC                |
| 5                                                             | KS, NE, IA, MO                                                                              | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6                                                             | MN, WI, IL                                                                                  | National Government Services, Inc. (NGS)          |
| H (4 & 7)                                                     | LA, AR, MS, TX, OK, CO, NM                                                                  | Novitas Solutions, Inc.                           |
| 8                                                             | MI, IN                                                                                      | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9)                                                         | FL, PR, VI                                                                                  | First Coast Service Options, Inc.                 |
| J (10)                                                        | TN, GA, AL                                                                                  | Palmetto GBA, LLC                                 |
| M (11)                                                        | NC, SC, WV, VA (excluding below)                                                            | Palmetto GBA, LLC                                 |
| L (12)                                                        | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                           |
| K (13 & 14)                                                   | NY, CT, MA, RI, VT, ME, NH                                                                  | National Government Services, Inc. (NGS)          |
| 15                                                            | KY, OH                                                                                      | CGS Administrators, LLC                           |